IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

OUTSOURCING FACILITIES ASSOCIATION, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil Action No. 4:25-cv-174-P

Plaintiffs' Reply in Support of a
Preliminary Injunction and Stay Pending Review

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Introduction

[redacted] the FDA's Delisting Action was arbitrary and capricious for the reasons stated in plaintiffs' motion. [redacted] Remarkably, [redacted] As the FDA explains (at 14), [redacted] Rather than rationally address these central facts, the FDA buried its head in the sand to disregard them.

That's not all the FDA disregarded. The FDA disregarded (and continues to disregard) [redacted] —proof positive of a shortage. Confirming that fact, and also disregarded by the FDA, is the [redacted] And that, in turn, was consistent with the scores of screenshots—[redacted]—from the websites of the largest national wholesalers in October and November 2024 showing that Ozempic and Wegovy were not in stock or that the supply was severely limited. [redacted] [1] At an absolute minimum, the FDA was obligated to tackle this evidence head-on, rather than brush it off. Its failure to do so was the height of unreasoned agency decisionmaking.[2]

[1] Citations to "App." refer to the Appendix filed with plaintiffs' Motion. ECF No. 39. Citations to "Supp. App." refer to plaintiffs' Supplemental Appendix filed with this brief.

[2] Plaintiffs agree with the FDA's proposal to consolidate a hearing on plaintiffs' motion for a preliminary injunction with adjudication on the merits pursuant to Federal Rule of Civil Procedure 65(a)(2).

Argument

I. Plaintiffs Are Likely To Succeed on the Merits

A. The Delisting Action Is Arbitrary and Lacks a Reasoned Basis

The Decision is arbitrary and capricious. Far from "toothless," arbitrary and capricious review "has serious bite." *Louisiana v. United States Dep't of Energy*, 90 F.4th 461, 470 (5th Cir. 2024) (cleaned up). Courts "must set aside agency action if the agency entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Sw. Elec. Power Co. v. EPA*, 920 F.3d 999, 1013 (5th Cir. 2019) (citation omitted). The Decision here checks all these boxes.

1. [redacted] That was arbitrary in itself. Worse, [redacted] This failure cuts to the heart of the Decision's rationale.

First and foremost, it upends the FDA's bottom-line determination that Novo Nordisk's supply is sufficient to satisfy market demand. The FDA concedes (at 14) that the current volume of compounding is relevant to projected demand. [redacted]

[redacted]

To put it plainly: [redacted] That's another thing FDA disregarded.

[redacted] the FDA cannot reverse itself now. "[J]udicial review of agency action is limited to the grounds that the agency invoked when it took the action." *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 591 U.S. 1, 20 (2020) (cleaned up). Nor would a reversal on this point, as Novo Nordisk proposes (at 5–6), comport with the statutory scheme. The compounding authorized during shortages is for drugs that are "essentially a copy" of approved drugs. 21 U.S.C. § 353b(a)(5); *see also* 21 U.S.C. § 353a(b)(1)(D). The statute permits compounding during a shortage so that some of "the" demand for "the drug" can be satisfied by compounded copies. 21 U.S.C. § 356c(h)(2). To

redefine that same demand as not part of the demand would redefine shortages out of existence as soon as they are declared.

2. The FDA and Novo Nordisk also cannot justify [redacted]

As plaintiffs' opening brief explained (at 12), [redacted] The FDA ignores the point, and Novo Nordisk essentially confirms it, [redacted]

[redacted]

See Louisiana, 90 F.4th at 477 (an "agency may not rely on impermissible post hoc rationalizations for its actions" (quotation marks omitted)). [redacted]

3. [redacted]

[redacted]

4. [redacted] But, as plaintiffs opening brief pointed out (at 8), [redacted]

5. [redacted]

Plaintiffs' opening brief pointed out (at 14) that [redacted]

[redacted] Significantly, the FDA (at 14–15) "largely agree[s]."

[redacted]

[redacted] But that does not answer whether Novo Nordisk has sufficient supply to satisfy the extraordinary demand for these products. When household toilet paper was in shortage during the first months of the pandemic, there is no doubt that manufacturers, wholesalers, and retailers had substantial "inventories," in that at any given moment there was an enormous amount of product moving through the supply chain. But that inventory did not mean that toilet paper was not in shortage then, just like Novo Nordisk's inventory does not mean that Ozempic and Wegovy are not in shortage now.

6. As discussed in plaintiffs' opening brief (at 16–18), [redacted] The FDA and Novo Nordisk dismiss the screenshots showing that wholesalers lacked sufficient supply of Ozempic and Wegovy, but far from demonstrating a localized supply disruption, the screenshots cover the three largest *national* wholesalers. *See* App. 237–48. The FDA notes (at 15) that the screenshots are dated October 30th to November 15th. (Without notice and comment, third parties had no idea what time period the FDA was considering.) But the FDA fails to comprehend that the screenshots [redacted]

[redacted] In short, the FDA "treated conflicting evidence here with an almost breathtaking lack of evenhandedness," *Sutter E. Bay Hosps. v. NLRB*, 687 F.3d 424, 437 (D.C. Cir. 2012), warranting vacatur and remand.

B. FDA Unlawfully Promulgated the Delisting Action by Failing To Undertake Notice and Comment

The Delisting Action required notice-and-comment. The FDA and Novo Nordisk do not dispute that there were no parties to this so-called "adjudication," and that the Delisting Action applies "not to any individual parties" but an entire industry, *Safari Club Int'l v. Zinke*, 878 F.3d 316, 333 (D.C. Cir. 2017). FDA and Novo Nordisk cite *dicta* in a case involving a bog-standard adjudication of party petitions seeking relief that, collaterally and through *res judicata*, also affected other parties. *City of Arlington v. FCC*, 668 F.3d 229, 243 (5th Cir. 2012) (discussing *Qwest Services Corp. v. FCC*, 509 F.3d 531 (D.C. Cir. 2007)). The same case recognized that adjudication involves an agency's determination of "rights . . . of parties properly before it" and cannot be "divorced from any specific application of the statute." *Id*. at 242, 243.

The FDA and Novo Nordisk do not show that Congress "expressly," 5 U.S.C. § 559, displaced the APA's notice-and-comment provisions in Section 506E. The directive to keep the shortage list "up-to-date" certainly did not, especially where the APA's "good cause" exception contemplates circumstances requiring expedition. The statute's incorporation of confidentiality provisions does not make notice-and-comment impossible, and the same goes for FDA's limited discretion to withhold information from the public. FDA has zero authority for its position that provisions authorizing confidentiality in limited circumstances evince any intent to override the APA.

Both FDA and Novo Nordisk ignore the Fifth Circuit's holding that no showing of prejudice is necessary. *W & T Offshore, Inc. v. Bernhardt*, 946 F.3d 227, 237 (5th Cir. 2019). In any event, the prejudice here is plain. For example, the parties had no idea what time period the FDA was considering. Novo Nordisk is also wrong that plaintiffs' argument is a Catch-22. *See*

Louisiana, 90 F.4th at 475 ("The Supreme Court held that the rescission was arbitrary and capricious *even if* DACA and DAPA were unlawful." (emphasis in original)).

II. The Equitable Factors Weigh Heavily in Favor of an Injunction and Stay

The FDA does not dispute that FarmaKeio and OFA members will be irreparably harmed, and the Court found as much in its Tirzepatide decision. Novo Nordisk's argument (at 20–21) that pharmacies like FarmaKeio are not permitted to compound essential copies of tirzepatide during a shortage has no place in this case. *See* Tirzepatide Order at 29 n.14. The FDA (correctly[5]) understands that FarmaKeio has that right when semaglutide is in shortage. *See* FDA.Opp.5. Without an injunction, the FDA will pursue compounding of essential copies by FarmaKeio, but it will not with an injunction. That is classic irreparable harm. And plaintiff OFA's members are outsourcing facilities that Novo Nordisk concedes may compound essential copies during a shortage. *See* Rosebush Supp. Decl. ¶ 3, Supp. App. 1.

FDA and Novo Nordisk's balance-of-equities arguments add nothing to their position on the merits. If they are wrong on the likelihood of success, then an injunction would not give effect to "the balance Congress struck," FDA.Opp.24, because Congress specifically chose to lift restrictions on compounding during a shortage, FDA.Opp.4. Consistent with Congress's determination that compounding should be permitted during a period of shortage, the public and private interests weigh in favor of an injunction because semaglutide is still in shortage.

Conclusion

The Court should enter a preliminary injunction and stay of FDA's Delisting Action.

[5] Section 503A prohibits compounding "essential[] copies of a commercially available drug product," 21 U.S.C. § 353a(b)(1)(D), and products in shortage are not commercially available. *See* Webster's New World College Dictionary (4th ed. 2007) ("available" means "that can be gotten, had, or reached; handy").

Dated: April 17, 2025

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